DESIGN AND DEVELOPMENT OF CUSTOMIZED PROSTHESIS UTILIZING ADDITIVE MANUFACTURING

Synopsis

submitted in the partial fulfilment for the requirement of

Doctor of Philosophy

in

Mechanical Engineering

Submitted by

Bobby Tyagi

Under the supervision of

Prof. Rahul Swarup Sharma
(Supervisor)

&

Dr. Ankit Sahai
(Co-Supervisor)
Associate Professor

Department of Mechanical Engineering, Faculty of Engineering

Dayalbagh Educational Institute (Deemed University)

Dayalbagh, Agra (UP) – 282005

2022

Research title

Design and Development of Customized Prosthesis utilizing Additive Manufacturing

Summary

Amputation places a heavy health impact on families, society, and healthcare systems. It has been estimated that there are roughly 0.62 amputees in India per thousand populations. This translates to one million individuals with amputations in the country. India is a nation where the exorbitant cost of prosthetics prevents disabled people from receiving the right care. Amputation is seen as a sign of social pariah in India, and amputees are considered a liability. Under a lack of psychological consultancy, the amputees start losing their self-confidence. Prostheses are critical devices in assisting people with disabilities, and prosthetic wearers commonly wear silicon liners between socket and limb. At the moment, liners are not specifically made to fit a person. At the stump-socket contact, it is believed that a flexible liner that might adhere to the residuum more precisely might enhance skin health. People who use traditional prosthetic sockets and liner technologies frequently experience discomfort since they are created using a non-quantitative, craftsman methodology that is labour-intensive and time-consuming. As a resolution to this difficulty, this research focuses on improving the process for the manufacturing of comfortable prosthetics and its liner using digital design involving CAD/CAM methodology, Additive Manufacturing (AM) technologies. As a result, prosthetic sockets, and liners are more widely available, cost-effective, highly personalized to a user's comfort, and better at adjusting and fitting to a developing body.

In this research, we propose a digital socket production workflow comprising the following steps:

1. 3D scanning of residual Limb
2. CAD modelling of the prosthetic socket, and liner interface
3. AM fabrication of a prosthetic socket, liner, and prosthetic feet above 1-2

Introduction

Medical prosthetics have been advancing since they were first purportedly utilized 3500 years ago in 950 B.C. [1]. Iron and wood have been replaced by lighter and stronger polymers (PLA & ABS) and composites. With the advancement of technology, the requirement for more ergonomic and dynamic designs that permit greater functionality has arisen [2]. The innovation consolidated into prosthetics has

additionally advanced; nonetheless, strolling into a prosthetist's office, one can discover the craftsmanship and expertise that goes into every patient's prosthetics without much of a stretch. Despite headways in technology, traditional strategies are being utilized by hit and trial techniques, so patients' prosthetics fit perfectly.

There is a growing need for prosthetics due to an aging population and veterans injured in recent conflicts and accidents. In 1981 [3], a survey revealed that approximately half a million people were amputees. The number of people with no prostheses was increasing by 17000 annually. In the United States, the American Academy of Orthotics and Prosthetists reports that the number of people using prostheses is expected to grow from 1.5 million in 1995 to 2.6 million in 2020. In 2014, it was observed that 30 million people required prosthetic and orthotic devices [4]. In India alone, 230,000 patients required prosthetic care. In India alone, 230,000 patients required prosthetic care [5]. In the present scenario, approximately 10 million Indians live with movement impairment. According to the statistical profile of people with disabilities in India [6], 2% of the general population is disabled, out of which 40% have movement disabilities as shown in fig 1.

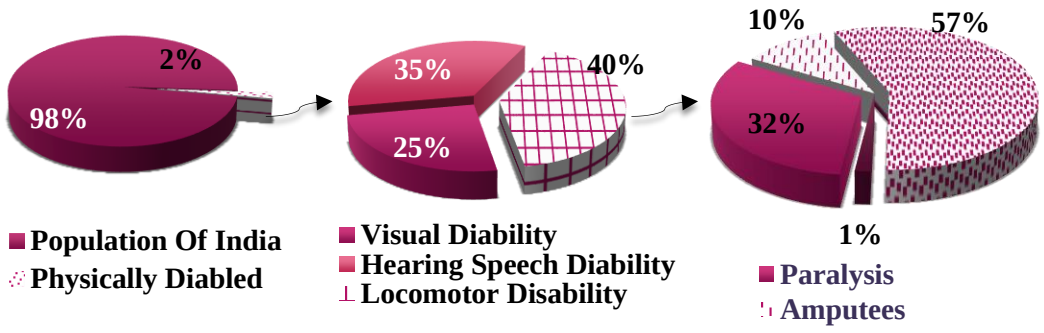

Fig 1 Percentage of the population suffering from disabilities

According to the WHO report, only 10% of disabled people have access to assistive products [7]. Several studies show that admittance to assistive gadgets is a significant variable in working on debilitated individuals' quality of Life (QOL). Appendage assistive gadgets help versatility, and a positive connection was seen between versatility and QOL. NGOs like Hardayal Viklang Sewa Kendra, Mahavir Seva Sadan, Jyot charitable trust, Bhagwan Mahaveer Viklang Sahayata Samiti, and Mukti M.S.Dadha

Foundation provide prosthetics for people with movement impairment. They use conventional (primarily mechanical) processes for manufacturing limb prosthetics as shown in fig 2.

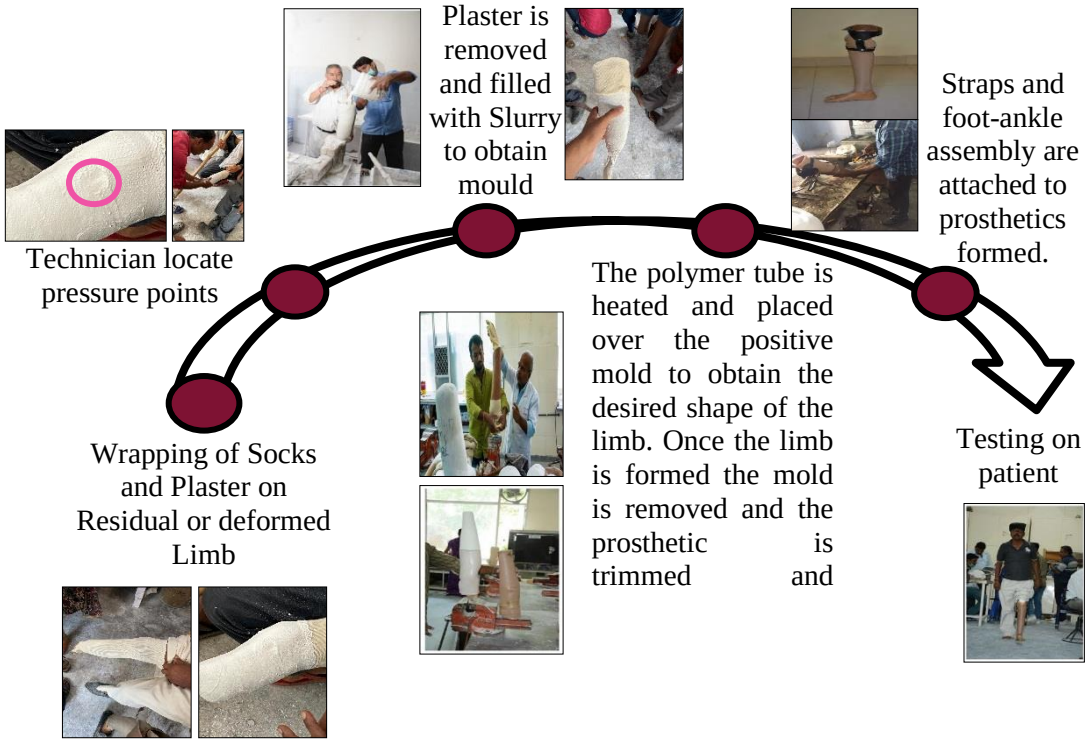
Technician locate pressure points
Wrapping of Socks and Plaster on Residual or deformed Limb
Plaster is removed and filled with Slurry to obtain mould
The polymer tube is heated and placed over the positive mold to obtain the desired shape of the limb. Once the limb is formed the mold is removed and the prosthetic is trimmed and
Straps and foot-ankle assembly are attached to prosthetics formed.
Testing on patient

Fig 2 Conventional Method Workflow for Manufacturing Prosthesis

Conventional method workflow has some limitations such as:

1. The traditional method is labour-intensive and lot of time it takes to supply services because it involves numerous manual procedures from mold development to ultimate testing.
2. The patient's leftover limb is encased in plaster to determine the size of the limb, which could be uncomfortable for them.
3. To get the prosthetic, the patient must return to the facility several times or stay there for a few days.
4. The entire process must be performed for each new prosthesis to be made for a specific patient, which causes discomfort for the patient.
5. The lack of regional service centres increases travel time and service times.

The demand for more effortless and naturally moving limbs is increasing daily. To overcome the challenges of conventional manufacturing processes, new proposed system, as shown in fig 4, will be used to meet the expectations. The proposed system will reduce the time of fabrication of prosthesis

from few months to few days. Emphasis is being laid on loading, stress, and strain of prosthetic sockets to enable the end-user to replicate their lost limb's functionality or correct the deformity of their foot. A significant issue in developing sockets and prosthetic liners is to meet the level of personalization. Each individual has different characteristics of a leftover limb which makes the requirement for personalization high. According to the Zion market research report, the artificial limbs market in 2018 was valued at USD 1970 million and is expected to reach USD 2758 million by 2024.

Apart from road accidents, there could be several reasons as shown in fig 3 like gangrene, diabetes mellitus, PVD, wound infection, and so on for loss of limb [8] and causes such as cerebral palsy Past injury in the spinal cord, History of stroke, Spine deformities, Arthritis, Fracture injury, Paralysis, Impaired muscles for deformities in a limb.

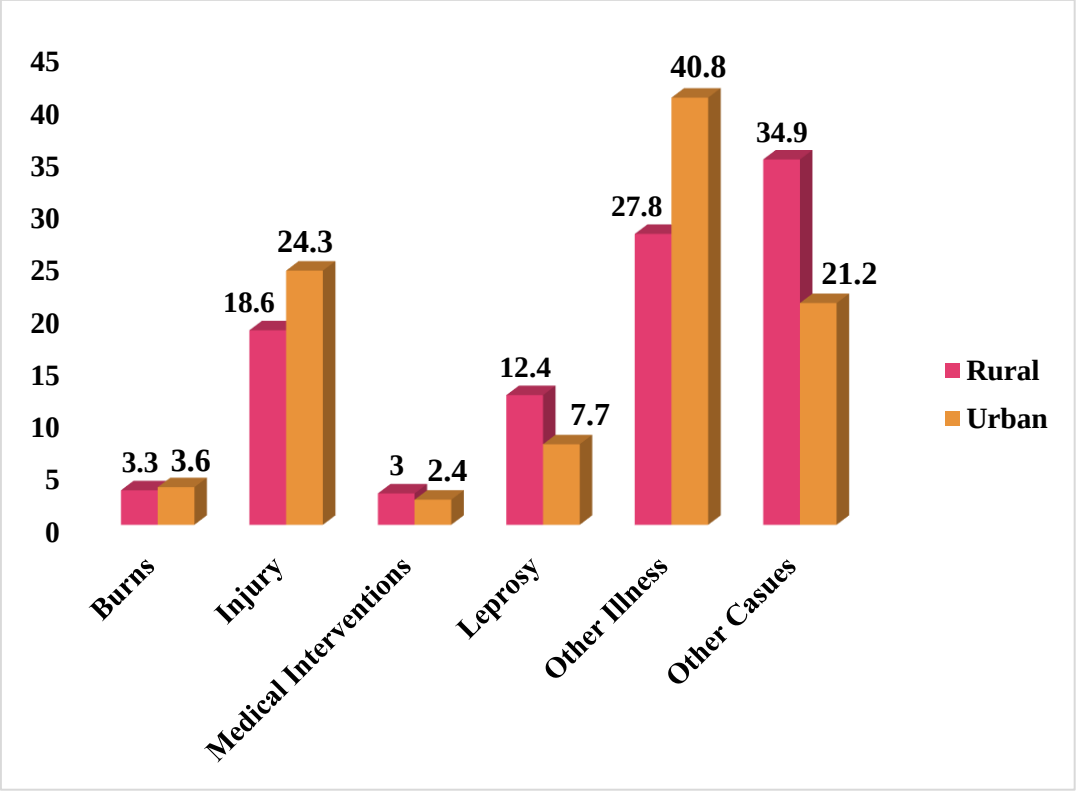

Fig 3 Cause of Amputation and Limb Deformity in Rural and Urban Areas

For patients, it is indisputable that prosthetics should be made lightweight and strong to keep patients protected and comfortable. Care should be taken while planning the prosthetic attachment as it is the point of contact between the residual limb and prosthetic socket. It is seen that inappropriate designs can cause wounds due to consistent bursts between the skin and prosthetic and the friction on the skin [9]. So, to avoid this, a residuum liner is used. A residual liner serves as an interface for amputees using

prosthetic limbs. The amount of time an amputee spends using their artificial limbs daily depends on how comfortable their prosthetic liners are, which can also stop additional pathological problems. This liner's function is to facilitate proper fitment. The residuum is enclosed and cushioned using a variety of silicon "socks" currently used before being inserted into the prosthesis socket. Traditional socks are not soft and comfortable, and they are not specifically made for each person, which can lead to tissue damage and skin irritation [10].

Objectives

1. Study and analysis of the effects of controllable process parameters of the material and AM process.
2. Design and fabrication of personalized prosthetic socket using AM for a better fit, which meets the requirement of patients.
3. Design and fabrication of a comfortable, accessible, versatile, and affordable prosthetic Liner using AM, which meets the requirement of patients.
4. To develop an accessible, novel comprehensive framework and pilot-scale demonstration of an improved process for fabricating improved prosthetic socket and prosthetic liner using AM.

Keywords: Additive manufacturing, Prosthetic Liner, Prosthetic Socket.

Literature review

The most significant problem with using a prosthetic, according to prosthetics users, is the socket fit [11–13]. A fluctuation volume of leftover limb is a major cause of socket fit issues. The human body is a dynamic system that is continually changing [14–16], thus traditional prosthetic sockets have an inflexible, definite volume [17]. Several creative methods for routine activities and novel answers to issues for which conventional technologies cannot offer a solution [18] have been made possible by the growth of three-dimensional (3D) printing [19–21] in the prosthetics business. The typical approach now utilized to design and create the prosthetic socket has two main drawbacks: one is associated with a high manufacturing cost [22]. In contrast, the other is associated with the quality of the socket fit [23]. Elastomeric liners [24] are commonly worn between socket and limb by prosthetic wearers. This is due to their superior skin adhesion, load distribution, and ability to form a seal. Laboratory investigations indicate that elastomeric liners, which are soft in compression and equivalent to biological tissues, permit less shear stress on the skin and offer a higher padding effect on bony prominences [25].

However, they also make you perspire more [26], reduce hygiene [27], and increase skin irritations. Amputees often comment that current commercially available prosthetic liners and sockets insulate their residual limbs [28]. In general, prosthetic wearers experience a wide range of dermatological issues linked with lower limb prostheses, including ulcers, cysts, and contact dermatitis. These issues are made worse by the enclosed space of a fitted socket, where sweating is trapped, and bacteria can grow [29]. The issue of overheating must be resolved in order to solve these issues. Previous work has shown that for effective thermal management of the socket environment, an active heat removal system is required [30], yet this is not available. Additionally, liners are not presently made to fit a particular person. The skin condition at the stump-socket junction and topographical tracking potential may both be improved by a smart liner that conforms to the residual material more precisely.

The objective is to design and development of customized prosthesis utilizing additive manufacturing as shown in fig 4 to overcome the limitations and disadvantages of the current practice, mainly related to the high production cost and subjective design criterion.

Methodology

1. Literature survey and analysis of the latest advancements in the design, manufacturing, and testing of the prosthetic socket, liner, and feet.
2. The number of disabled people who use prosthetics will be interviewed in Agra and Jaipur to get information on the challenges they are experiencing.
3. Visiting medical camps at NGOs like Hardayal Viklang Kendra and Baghwan Mahaveer Viklang Seva Samiti (Jaipur Foot Org.) to identify cases.
4. Development of experimental test bench for personalized prosthetic socket and its liner fabricated using AM.
5. Analysis of multiple materials for manufacturing of prosthetic socket and its liner.
6. Mechanical characterization and strength co-relationship of different lightweight/ nano-composites/ fiber-reinforced materials for AM of the prosthesis.
7. Fabrication of personalized prosthetic socket and its liner for a patient.
8. Rigorous testing of fabricated parts includes mechanical testing (like tensile, compression, and impact test) and surface morphology (like fractography using SEM).

9. Clinical evaluation of prosthetic liner and Orthosis manufactured by Additive Manufacturing.

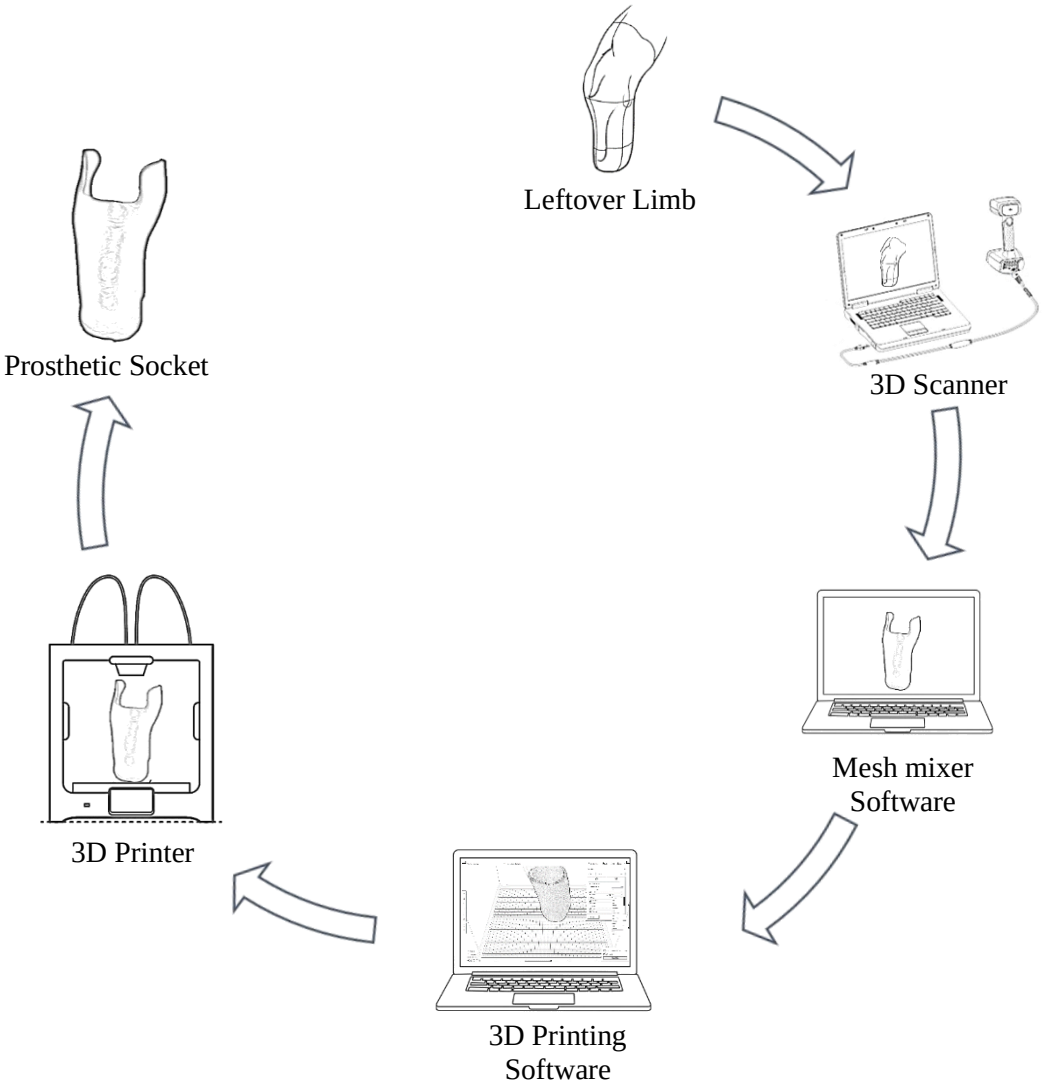

Fig 4 Proposed workflow diagram for design and fabrication of prosthesis

Likely impact of the research work

The proposed research will improve and standardize additive manufacturing technology to fabricate a prosthetic socket and its liner. It will make India self-reliant in the field of additive manufacturing for prosthetics. It will be a step towards a new era of growth and innovation in India and a new milestone in the Make in India campaign. The planned work's output would undoubtedly offer impetus to make the technology cost-effective so that it may thrive in the Indian market, making it an outstanding job facilitator and promoting the establishment of start-ups and entrepreneurs in India. Significant research and development are required to investigate new additive manufacturing setup designs and fabrication process parameters to manufacture personalized prosthetic and prosthetic liners at a low cost.

Expected output and outcomes of the research work:

1. The proposed work shall bring rehabilitation possibilities to people who have had access to the prosthesis. This will be a step forward to restoring normalcy in their lives, helping them return to the usual routine and mainstream lifestyle, and restoring their declining self-worth.
2. In the proposed research, technicians shall visit remote areas, conduct digital scans on-site using a handheld scanning device and bring in the digital 3D model of the limb. Then a prosthetic socket and the prosthetic liner will be produced using the scanned model and sent to the patient. This will prevent the amputees from hauling around a facility or NGO far away from their place of stay under much discomfort to themselves and their guardians.
3. The proposed work will enable the fabrication of personalized prostheses and prosthetic liners.
4. The proposed research and experimental studies will lead to innovation ready for pilot-scale demonstration of fabricated prostheses and prosthetic liners.
5. Reduction in dependence on the international market and making India self-reliant in the sector of Prosthetics through the integration of additive manufacturing.
6. High-impact journal publications and the filing of patents.

References

1. K. Norton, InMotion 17, 1 (2007).
2. Finch, Lancet 377, 548 (2011).
3. D. Mohan, Orthot. Prosthetics 40, 16 (1986).
4. World Health Organisation and International Society for Prosthetics and Orthotics, WHO Libr. Cat. Data 1 (2005).
5. S. G. Moulic, S. Singh, R. Hussain, G. Murthy, Y. Khawade, and N. Bettaiah, J. 3D Print. Med. 3, 185 (2019).
6. G. of I. Ministry of Statistics and Programme Implementation, National Sample Survey, 0 (2016).
7. P. Standards, WHO Standards for Prosthetics and Orthotics (2017).
8. A. K. Katiyar, H. Agarwal, P. Priyadarshini, A. Kumar, S. Kumar, A. Gupta, B. Mishra, R. Aggarwal, K. D. Soni, P. Mathur, R. Sagar, A. Srivastava, N. Banerjee, and S. Sagar, Int. Wound J. 17, 419 (2020).

9. S. Sankaran, P. R. Murugan, J. C. Johnson, H. J. S. Abdullah, C. M. N. Raj, and D. Ashokan, Proc. 2019 IEEE Int. Conf. Commun. Signal Process. ICCSP 2019 77 (2019).
10. V. Dhokia, J. Bilzon, E. Seminati, D. C. Talamas, M. Young, and W. Mitchell, in Procedia CIRP (Elsevier B.V., 2017), pp. 476–481.
11. E. Schaffalitzky, P. Gallagher, M. MacLachlan, and S. T. Wegener, Disabil. Rehabil. 34, 2085 (2012).
12. L. E. Pezzin, T. R. Dillingham, E. J. MacKenzie, P. Ephraim, and P. Rossbach, Arch. Phys. Med. Rehabil. 85, 723 (2004).
13. G. K. Klute, C. Kantor, C. Darrouzet, H. Wild, S. Wilkinson, S. Iveljic, and G. Creasey, J. Rehabil. Res. Dev. 46, 293 (2009).
14. J. W. Steer, P. R. Worsley, M. Browne, and A. Dickinson, Prosthet. Orthot. Int. (2020).
15. B. G. Larsen, K. J. Allyn, M. A. Ciol, and J. E. Sanders, J. Prosthetics Orthot. 33, 3 (2021).
16. E. J. Weathersby, A. C. Vamos, B. G. Larsen, J. B. McLean, R. V Carter, K. J. Allyn, D. Ballesteros, H. Wang, N. S. deGrasse, J. L. Friedly, B. J. Hafner, J. L. Garbini, M. A. Ciol, and J. E. Sanders, J. Rehabil. Assist. Technol. Eng. 9, 205566832210932 (2022).
17. E. Nickel, K. Barrons, B. Hand, A. Cataldo, and A. Hansen, Prosthet. Orthot. Int. 44, 355 (2020).
18. P. C. Liacouras, D. Sahajwalla, M. D. Beachler, T. Sleeman, V. B. Ho, and J. P. L. Iii, 1 (2017).
19. P. K. Penumakala, J. Santo, and A. Thomas, Compos. Part B Eng. 201, 108336 (2020).
20. P. Deepa, IOSR J. Mech. Civ. Eng. 5, 62 (2014).
21. J. Barrios-Muriel, F. Romero-Sánchez, F. J. Alonso-Sánchez, and D. R. Salgado, Materials (Basel). 13, (2020).
22. G. M. Berke, J. Fergason, J. R. Milani, J. Hattingh, M. Mcdowell, V. Nguyen, and G. E. Reiber, J. Rehabil. Res. Dev. 47, 361 (2010).
23. L. Lorenzelli, G. Sordo, A. Bagolini, and G. Resta, Proc. - 2017 1st New Gener. CAS, NGCAS 2017 233 (2017).
24. L. Paternò, V. Dhokia, A. Menciassi, J. Bilzon, and E. Seminati, Biomed. Eng. Online 19, (2020).
25. G. K. Klute, B. C. Glaister, and J. S. Berge, (2010).
26. R. Caldwell and S. Fatone, J. Prosthetics Orthot. 29, 145 (2017).

27. C. M. Webber and B. L. Davis, J. Biomech. 48, 1294 (2015).

28. C. M. Webber, M. R. Klittich, A. Dhinojwala, and B. L. Davis, J. Prosthetics Orthot. 26, 212 (2014).

29. N. L. Dudek, M. B. Marks, S. C. Marshall, and J. P. Chardon, 86, (2005).

30. R. J. Williams, E. D. Washington, and C. Holloway, 1 (2017).